K041405

SEP - 2 2004

8. 510(k) Summary.

8.1. Submitter's identification.

- Industrial & Medical Design, Inc.
  2570 Corporate Pl., Suite E104
  Monterey Park, CA 91754

- Contact person: Yevgeniy Kuklin
  President

- Date Summary Prepared: April 9, 2004

8.2. Submitted device name.

- Trade name: Aspiration Pump

- Classification name: Powered Suction Pump,
  21 CFR § 878.4780

8.3. Identification of predicate device.

- Company: Medela AG
- Device: Basic 30
  510(k) K021368

8.4. Device description.

The Aspirating Pump consists of battery powered microprocessor controlled diaphragm pump, pressure release valve, and disposable collection chamber with bacterial filter and overflow protection. Suction tubing from a patient connected to collection chamber by means of lure connector.

8.5. Intended use of the device.

The Aspiration Pump is indicated for vacuum extractions, aspiration and removal of surgical fluids, bodily fluids, or infection materials during surgical procedures.

8.6. Rationale for Substantial Equivalence.

The Aspiration Pump shares the same general indications for use, similar design features, and functional features as predicated device.
Therefore, the technological differences between Aspiration Pump and predicated device do not raise any new issues of safety, effectiveness, or performance of the product. We believe that Aspiration is substantially equivalent to the above legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Yevgeniy Kuklin
President
Industrial & Medical Design, Inc.
2570 Corporate Place, Suite E104
Monterey Park, California 91754

Re: K041405
Trade/Device Name: Aspiration Pump
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: BTA
Dated: August 6, 2004
Received: August 16, 2004

Dear Mr. Kuklin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041405

Device Name: Aspiration Pump

Indications For Use:

The Aspiration Pump is indicated for vacuum extractions, aspiration and removal of surgical fluids, bodily fluids, or infection materials during surgical procedures.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041405